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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LEWIS, PATRICK T	

ART UNIT	PAPER NUMBER
1623	

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19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/802,779	HILDRETH, JAMES E.	
	Examiner	Art Unit	
	Patrick T. Lewis	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,19-30,33-37 and 40-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,19-30,33-37 and 40-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Objections/Rejections Set For the in Office Action dated October 22, 2002

1. Claims 1-15, 19-30, 33-37, and 40-51 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-15, 19-20, 22-30, 33-37, and 40-45 of copending Application No. 09/801,393 ('393). Although the conflicting claims are not identical, they are not patentably distinct from each other.

Regarding claims 1-4, 6-15, 19-20, 22-30, 33-34, and 36, the instantly disclosed invention differs from '393 (claims **1-4, 6-15, 19-20, 22-30, 33-34,** and **36**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32).

Regarding claim 5, the instantly disclosed invention differs from '393 (claim **3**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin and is not limited to a method wherein the virus is *Herpes simplex* virus. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* (page 3, lines 16-20).

Regarding claim 21, the instantly disclosed invention differs from '393 (claim **20**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of

a β-cyclodextrin and is not limited to a method wherein the virus is *Herpes simplex* virus or HIV. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* or HIV (page 3, lines 16-20).

Regarding claim 35, the instantly disclosed invention differs from '393 (claim **35**) in that '393 is drawn a method utilizing a composition comprising about 30 mM or less of a β-cyclodextrin and is limited to a method wherein the virus is HIV. However, the instant disclosure teaches that composition of the method generally utilizes about 5 to 30 mM β-cyclodextrin as the active agent (page 28, lines 31-32) and is used in methods wherein the virus is *Herpes simplex* or HIV (page 3, lines 16-20).

Regarding claim 37 and 46-49, the instantly disclosed invention differs from '393 (claim **37**) in that '393 is drawn to a composition comprising about 30 mM or less of a β-cyclodextrin and an agent. However, the composition of '393 consists essentially of a β-cyclodextrin, as the agent is not required for treating a sexually transmitted disease but may be optionally included (see page 25-27 of '393). '393 further discloses that the β-cyclodextrin can be formulated in any pharmaceutically acceptable carrier, provided that the carrier does not affect the activity of the β-cyclodextrin in an undesirable manner. Thus, the composition can be, for example in the form of a cream, a foam, a jelly, a lotion, an ointment, a solution, a spray, or a gel (page 25, lines 30-32 and page 26, lines 1-15). '393 further teaches that the amount of cyclodextrin used in the composition is about 1 to 100 mM, generally about 5 to 30 mM (page 28, lines 5-20).

Regarding claims 40-41 and 43-45, the instantly disclosed invention differs from '393 (claims **40-41** and **43-45**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. However, the instant disclosure teaches that composition comprises about 0.1% to 3% of a β-cyclodextrin as the active agent (page 29, lines 2-9).

Regarding claim 42, the instantly disclosed invention differs from '393 (claim **42**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. '393 does not disclose the composition being a vaginal disk. However, the instant disclosure teaches that composition comprises about 0.1% to 3% of a β-cyclodextrin as the active agent (page 29, lines 2-9) and '393 teaches that the composition as being in a form suitable for topical administration to a subject, particularly intravaginal [vaginal disk] (page 25, lines 15-29)

Regarding claims 50-51, the instantly disclosed invention differs from '393 (claim **40**) in that '393 is drawn a composition comprising about 0.1% to 3% of a β-cyclodextrin and a solid substrate. However, the instant disclosure teaches that composition comprises about 0.1% to 3% [0.1 to 2 grams, generally 0.25 to 0.75 grams] of a β-cyclodextrin as the active agent (page 29, lines 1-9).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2. Claims 1-15, 19-30, 33-37, and 40-49 were rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in view of Baert et al. WO 97/18839 (Baert) and Sokal et al. US 5,819,742 (Sokal).

Claims 1-15, 19-30, 33-37, and 40-49 are directed to compositions consisting essentially of a β-cyclodextrin and methods of using such compositions to reduce the risk of transmission of a sexually transmitted disease.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other pathogens to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The formulation acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable to the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that: 1) Bergeron does not limit its disclosure to β-cyclodextrins, but is drawn to cyclodextrins in general. Bergeron does not disclose the use of a 2-hydroxypropyl –β-cyclodextrin; 2) Bergeron does not teach the amounts of cyclodextrin used (teaching is silent on amounts used) 3) Bergeron does not teach the composition being formulated into a suppository, film, condom, suppository, bioadhesive polymer, diaphragm, absorptive substrate, glove, sponge, or tampon. However, these deficiencies would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert and Sokal.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert includes loviride which is an art-recognized anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Baert further teaches the ratio of active ingredient to cyclodextin varies widely and that ratios of 1/100 [essentially cyclodextrin] to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

Sokal teaches a vaginal device (tampon) for providing physical and chemical barriers for protection against the sexually transmitted diseases (column 1, lines 56-58). The device is a towelette formed of an absorbent sheet material and a flowable preventive formulation incorporated into the towelette by absorption (column 1, lines 58-

63). The preventive formulation may include one or more pharmacologically active agents (column 1, lines 59-67).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the amounts claimed by applicant since β-cyclodextrins in these amounts (including 2-hydroxypropyl-β-cyclodextrin) are taught by Baert for pharmaceutical compositions which are useful for treating HIV-infected patients. It would have also been obvious to one of ordinary skill in the art at the time of the invention to formulate the composition disclosed by Bergeron into a film, glove, or condom since Bergeron teaches inclusion of a film-forming component in the formulations. Based on these teachings it would have been obvious to formulate the compositions of Bergeron into a film. It would have been equally obvious to further formulate the film into a glove or condom since gloves ("rubber gloves") and condoms are basically films and are recognized in the art for prevention of sexually transmitted diseases. It would have also been obvious to incorporate the composition into a tampon or sponge since Sokal teaches vaginal devices incorporating pharmacological agents for the prevention of the transmission of sexually transmitted diseases. One would have been motivated to do what applicant claims in order to provide an effective formulation for preventing sexually transmitted diseases in an already known and widely used form.

Applicant's R sponse dated April 11, 2003

3. In the Response filed April 11, 2003, claims 1, 9, 23, 37, and 40 were amended and claims 53-58 were added. Applicant presented arguments directed to the rejection of claims 1-15, 19-30, 33-37, and 40-51 under the judicially created doctrine of obviousness-type double patenting and to the rejection of claims 1-15, 19-30, 33-37, and 40-49 under 35 U.S.C. 103(a). Claims 1-15, 19-30, 33-37, and 40-58 are pending. An action on the merits of claims 1-15, 19-30, 33-37, and 40-58 is contained herein below.

4. Applicant's arguments filed April 11, 2003 have been fully considered and have overcome the rejection of claims 1-15, 19-30, 33-36, and 40-49 under 35 U.S.C § 103(a) as set forth in the Office Action dated June 26, 2002. The rejection of claim 37 is maintained for the reasons of record as set forth in the Office Action dated October 22, 2002.

5. The provisional Rejection of claims 1-15, 19-30, 33-37, and 40-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 09/801,393 ('393) is maintained for the reasons of record as set forth in the Office Action dated October 22, 2002.

Response to Arguments

6. Applicant's arguments filed April 11, 2003 have been fully considered but they are not persuasive. Applicant has traversed the provisional rejection of claims 1-15, 19-30, 33-37, and 40-51 under the judicially created doctrine of obviousness-type double

patenting on the grounds that a Terminal Disclaimer, disclaiming any term of a patent issuing from the '393 application, has been submitted.

The Terminal Disclaimer referred to in applicant's response, disclaiming any term of a patent issuing from the subject application that may extend beyond the term of a patent issuing from the '393 Application, has not been received and, as such, has not been made of record.

7. In regards to the rejection of claim 37 under 35 U.S.C. 103(a), applicant argues that the prior art does not teach a composition "consisting essentially of" a β-cyclodextrin wherein the β-cyclodextrin is the active agent.

The examiner respectfully disagrees. Claim 37 is drawn to a composition comprising a β-cyclodextrin and, optionally, an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant and a combination thereof. Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert includes loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Since the Office does not have the facilities for preparing the claimed materials and comparing themwith prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195

USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Claim Objections

8. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 55-56 have been renumbered 57-58.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 52-56 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-18 and 31-32

of copending Application No. 09/801,393 ('393). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The '393 application differs from the instantly claimed invention in that the instantly disclosed invention is drawn a method utilizing a composition consisting essentially of a β-cyclodextrin. However, the instant disclosure teaches that composition contains 1 to 100 mM (generally about 5 to 30 mM) β-cyclodextrin as the active agent (page 28, lines 31-32).

11. Claims 57-58 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 38-39 of copending Application No. 09/801,393 ('393). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The '393 application differs from the instantly claimed invention in that the instantly disclosed invention is drawn to a pharmaceutical composition consisting essentially of a β-cyclodextrin. However, the instant disclosure teaches that composition contains 1 to 100 mM (generally about 5 to 30 mM) β-cyclodextrin as the active agent (page 28, lines 31-32).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 52-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in combination with Baert et al. WO 97/18839 (Baert).

Claims 52-56 are directed to a method of reducing the risk of transmission of a sexually transmitted disease comprising contacting the pathogen or cells susceptible to infection by the pathogen with an effective amount of a compositions consisting essentially of a β-cyclodextrin and an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant and a combination thereof.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The composition acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The inhibitors are preferably encapsulated in a

liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that Bergeron does not limit its disclosure to β-cyclodextrins (drawn to cyclodextrins in general) nor are cyclodextrins taught as the active agent. The selection of a β-cyclodextrin to employ in the method taught by Bergeron would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert includes loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36).

Baert further teaches the ratio of active ingredient to cyclodextin varies widely and that ratios of 1/100 [essentially cyclodextrin] to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the method of Bergeron since β-cyclodextrins are taught by Baert for pharmaceutical compositions which are useful for treating HIV-infected patients. In regards to the "consisting essentially of" claim language, for the purposes of applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See MPEP 2111.03. The instantly claimed invention is seen to read upon methods for reducing the transmission of a sexually transmitted disease employing a composition comprising a b-cyclodextrin and an additional active agent. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

15. Claims 57-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergeron et al. U.S. Patent 6,068,851 (Bergeron) in combination with Baert et al. WO 97/18839 (Baert).

Claims 57-58 are directed to a composition consisting essentially of a β-cyclodextrin and an agent selected from a contraceptive, an agent for treating a sexually transmitted disease, a lubricant and a combination thereof.

Bergeron teaches a composition and method for preventing the transmission of pathogens through mucosae and/or skin, particularly human immunodeficiency virus and other sexually transmitted diseases (column 3, lines 14-21). Other diseases to be treated/prevented include herpes simplex virus, hepatitis (A, B, and C), *Chlamydia trachomatis*, and *Candida spp.* (Column 7, lines 9-50). The composition acts as a physical, chemical, and/or pharmacological barrier and comprises a film-forming component and a microbicide, spermicide, and/or any other drug effective against the pathogen (column 3, lines 34-67). The inhibitors are preferably encapsulated in a liposome, nanoparticle, or cyclodextrin (column 4, lines 1-14). Other active agents which may be used include antimicrobial agents such as antibiotics, antifungals, antivirals, and anti-inflammatory agents (column 6, lines 5-24). The pharmacological barrier may be used in the form of a gel that is applicable on the vaginal, cervical and/or ano-rectal muscosae to prevent transmission of the pathogen and comprises inhibitors of HIV protease and reverse transcriptase. The copolymer poloxamer 407 is a chief component of the gel formulation (column 4, lines 15-25). The formulations may include any film-forming component and/or microbicide and/or spermicide and/or any drug and/or liposomes (or other drug carriers) or any combination of these products (column 7, lines 40-50).

Bergeron differs from the instantly disclosed invention in that Bergeron does not limit its disclosure to β-cyclodextrins (drawn to cyclodextrins in general) nor are cyclodextrins taught as the active agent. The use of a β-cyclodextrin in the composition taught by Bergeron would have been obvious to the skilled artisan at the time of the invention in view of the teachings of Baert.

Baert teaches pharmaceutical compositions comprising a β-cyclodextrin (including 2-hydroxypropyl-β-cyclodextrin, see page 13, lines 5-6) and an active ingredient (page 9, lines 24-27). Baert defines the term "active ingredient" as being compounds or mixtures of compounds which are pharmaceutically or therapeutically or cosmetically active for treating humans or animals (page 4, lines 9-16). Active ingredients taught by Baert includes loviride which is an art-known anti-retrovirally active compound, particularly useful in treating HIV-infected patients (page 3, lines 35-36). Baert further teaches the ratio of active ingredient to cyclodextin varies widely and that ratios of 1/100 [essentially cyclodextrin] to 100/1 may be applied [compositions comprising ~4% (corresponds to 30 mM) included within this range] (page 11, lines 1-5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a β-cyclodextrin in the composition of Bergeron since β-cyclodextrins are taught by Baert for pharmaceutical compositions which are useful for treating HIV-infected patients. In regards to the "consisting essentially of" claim language, for the purposes of applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising". See MPEP

2111.03. The instantly claimed invention is seen to read upon methods for reducing the transmission of a sexually transmitted disease employing a composition comprising a b-cyclodextrin and an additional active agent. Since the Office does not have the facilities for preparing the claimed materials and comparing when with prior art inventions, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

Conclusion

16. Claims 1-15, 19-30, 33-37, and 40-58 are pending. Claims 1-15, 19-30, 33-37, and 40-58 are rejected. No claims are allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 8:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623

James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
June 28, 2003